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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VOGEL, NANCY TREPTOW	
ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,323	BOLLA ET AL.	
	Examiner	Art Unit	
	NANCY VOGEL	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-39 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-39, 43, 45, 47, 48* is/are rejected.

7)☒ Claim(s) *44, 46, 49, 50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/08 has been entered.

Claims 29-39, 43-50 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claim Rejections - 35 USC § 102

Claims 29, 30, 32-34, 36, 27, 43 rejected under 35 U.S.C. 102(b) as being anticipated by Barr et al.

It is noted that applicants have amended the claims to recite that the amino acid composition of the polypeptide include means for supplementing an animal diet according to the particular nutritional needs of the animal, the nutritional needs of the animal being ascertained by a feed analysis to determine the amino acid deficiency of the animal fed with a certain feed. It is considered that this limitation does not limit the composition of the polypeptide, since it could be considered that any polypeptide of

average length and composition would supplement any amino acid deficiciency of a feed source, since at least some of the amino acids which may be lacking in any particular feed source would be supplemented by said average polypeptide.

This rejection is maintained essentially for reasons made of record in the previous Office action with slight modifications.

To recapitulate, Barr et al. teach a transformed yeast strain (S. Cerevisiae strain AB110) comprising two different nucleic acid polymers (pAB24/P.vivax01 and pAB24/P.vivax-2) for encoding a polypeptide ordinarily exogenous to yeast under the control of a promoter, said nucleic acid polymer encoding a polypeptide comprising a plurality of amino acid residues that would supplement a feed source for and animal diet. The expression of the polypeptide is inducible upon growth in culture medium comprising 1% glucose (page 1162, lines 23-24). Barr et al. teach that said polypeptide is "held" by said strain, because Barr et al. were able to isolate the polyeptpdes from yeast extracts (pages 1164, Fig. 2, par. bridging p. 1164-1165, and page 1165, Fig. 3). Barr et al. teach such a transformed yeast strain wherein said strain is auxotrophic, but was non-auxotrophic prior to transformation (page 1162). The promoter is a GAPDH hybrid promoter (p. 1162, lines 6-11). Barr teach a method for producing a yeast additive comprising inserting such a contruct into a yeast strain and expressing the gene in said construct (see 1161-1162 and 1164-1165, Figs. 2 and 3).

Applicants arguments filed 6/19/08 have been considered but have not been found convincing.

Applicants have argued that Barr "merely teaches a yeast strain transformed with a construct containing a gene encoding an exogenous" and "does not teach of suggest that the composition of the exogenous protein is as recited by the amended claims...wherein the amino acid composition is determined by a feed analysis". However, as was stated above, virtually any polypeptide would contain numerous amino acids which could supplement a food source for an animal, since the provision of amino acids would supplement any food source.

Claims 29-30, 32-34, 36-37, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Nussenzweig et al. (US Patent 4,826,957) as evidence by Barr et al. (both previously cited) .

This rejection is maintained essentially for reasons made of record in the previous Office action with slight modification. To recapitulate, Nussenzweig et al teach a transformed yeast strain *(Saccharomyces cerevisiae* strain ABII0) comprising a nucleic
acid polymer for encoding a polypeptide ordinarily exogenous to yeast *(P. vivax* circumsporozoite protein antigen) under the control of a yeast derived promoter (an ADH-2/GAPDH promoter hybrid), said nucleic acid polymer being a synthetic polymer said nucleic acid polymer encoding a polypeptide comprising a plurality of amino acid residues that would supplement a feed source for and animal diet.

(see entire document, especially Example 1 at column 9, lines 40-45; and column i0, lines 9-68). The construct for insertion into the yeast is referred to as *"pAB24/P. vivaxI-*

5" (see column i0, line 62). With regard to claim 30, the expression of the polypeptide is inducible upon growth in culture medium comprising YEP with 1% glucose (see paragraph bridging columns 10-11). This is evidenced by Barr et al who teach the same ADH-2/GAPDH hybrid promoter can induce expression of *a P. vivax* protein upon growth in medium containing 1% glucose at page 1162, lines 23-24: "[f]or induction and analysis of vivax-i CS protein, yeast cells were diluted 1:20 into medium containing 1% glucose and were grown for 36 h at 30°C" (see page 1162, lines 23-24 and page 1163, last paragraph; emphasis added). With regard to claim 32, Nussenzweig et al teach such a transformed yeast strain wherein said polypeptide is "held" by said strain because Nussenzweig et al were able to isolate the polypeptides from yeast extracts as confirmed by western blotting (see column ii, lines 2-37 and Figure 4). Regarding claims 33, Nussenzweig et al also teach such a transformed yeast strain wherein said strain is auxotrophic, but was non-auxotrophic prior to transformation (see column 10, lines 43-53). With regard to claim 36, the promoter is a GAPDH hybrid promoter (see, e.g., column I0, lines 28-36). Finally, with regard to claim 43, Nussenzweig et al also teach a method for producing a yeast additive comprising inserting such a construct into a yeast strain and expressing the gene in said construct (see above as well as Nussenzweig et al at column 10, lines 59-68 and column 11, lines 1-19).

Applicants arguments filed 6/19/08 have been considered but have not been found convincing. Applicants have argued that Nussenzweig "merely teaches the expression of an exogenous protein in yeast, nothing was mentioned with regard to the

means that is recited in Claims 29 and 37". However, as was stated above in the rejection over Barr et al, virtually any polypeptide would contain numerous amino acids which could supplement a food source for an animal, since the provision of amino acids would supplement any food source

Claims 29-32, 34, 36, 37, 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Tully et al. (US Patent 6,337,193) (previously cited).

This rejection is maintained essentially for reasons made of record in the previous Office action, with slight modifications. To recapitulate, Tully et al teach a transformed yeast strain comprising a nucleic acid polymer for encoding a polypeptide ordinarily exogenous to yeast under the control of a yeast derived promoter, said nucleic acid polymer selected from the group consisting of synthetic and natural nucleic acid polymers,), said nucleic acid polymer being a synthetic polymer and said nucleic acid polymer encoding a polypeptide comprising a plurality of amino acid residues that would supplement a feed source for and animal diet. (see entire document, especially Figures 2 & 5; column 2, lines 5-12
& 20-28; column 3, lines 18-36; and column 5, lines 40-45). Tully et al teach such a strain wherein the expression of the polypeptide is inducible, i.e., wherein the production of the MBP protein is under the control of the AOXI promoter which is inducible by methanol (see, e.g., column 5, lines 20-25). With regard to claim 31, Tully et al now anticipate Applicant's amended claim because Tully et al teach the use of integrative vectors which recombine into the yeast genome, i.e., one or more of the chromosomes

of the transformed yeast (see column 5, lines 60-67). Regarding claim 32, the polypeptide produced by the transformed yeast is "held" by the transformed yeast insofar as transformed cells that secret the protein would "hold" the protein for a given period of time before the protein is released into the culture medium. Regarding claim 34, the transformed yeast strain is *Pichia pastoris* (see, e.g., column 2, line 26-28). Regarding claim 36, the promoter utilized for the production of PDI is the GAPDH promoter (see, e.g., column 5, lines 15-45). Regarding claim 37, Tully et al also teach the construct for transforming a host organism (yeast) comprising a nucleic acid polymer for encoding a polypeptide ordinarily exogenous to said organism under the control of a yeast derived promoter, wherein the nucleic acid polymer is a plasmid and is used to make a protein that would be capable of supplementing an animal diet according to nutritional needs of the animal (see, e.g., Figures 2 & 5; column 2, lines 5-12 & 20-28; column 3, lines 18-36; and column 5, lines 40-45). Tully et al also teach a method for producing this yeast additive comprising inserting such a construct into a yeast strain and expressing the gene (see, e.g., Example 3, columns 11-14).

Applicants arguments filed 6/19/08 have been considered but have not been found convincing. Applicants have argued that Tully "does not disclose the claim limitation with regard to the specific compoisition of amino acids in the polyepptides". However, as is stated in the over Barr et al, virtually any polypeptide would contain numerous amino acids which could supplement a food source for an animal, since the provision of amino acids would supplement any food source. Therefore the rejection is maintained.

Claims 29-37, 39, 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (US Patent No. 5,985,605) (previously cited).

This rejection is maintained essentially for the reasons made of record, with slight modification.

Cheng et al. teach a transformed yeast strain comprising a nucleic acid polymer for encoding a polypeptide ordinarily exogenous to yeast (S. ruminantium JY35 phytase) under the control of a yeast derived promoter, said nucleic acid polymer selected from the group consisting of synthetic and natural nucleic acid polymers, and said nucleic acid encoding a polypeptide which would provide amino acids to supplement an animal feed product (see entire document, especially Fig 15, col. 5 lines 54-58, col. 3, lines 66-67 through col. 4, lines 1-15, col. 7, lines 44-65). Cheng et al. teach such a strain wherein the expression of the polypeptide is inducible (see col. 9 lines 11-36). Regarding claim 32, the polypeptide produced by the transformed yeast is retained in the yeast insofar as the transformed cells may or may not secrete the exogenous protein (see col. 7, lines 57-59). Regarding claim 34, the transformed yeast strain is P. pastoris of S. cerevisiae (see col. 7 lines 44-49). Regarding claims 35 and 39, the polypeptide comprises at least 3 methionines, 6 histidines, 2 threonine, 2 isoleucines 1 valine, and 1 tryptophan; or 6 lysines, 3 methionines or cysteines, 2 threonines, 1 valine, 2 isoleucine, 6 histidine, and 1 tryptophan (see Fig. 15). Regarding claim 36 a promoter utilized is GAPDH promoter. Regarding claim 43, Cheng et al. also teach a method for producing this yeast additive comprising inserting such a construct

into a yeast strain and expressing the gene (see col. 12, lines 56-67 and col. 13, lines 1-9).

Applicants have argued that for the reasons similar to those presented in the previous sections, applicant traverses this rejection because the '605 patent lacks teachings with regard to the compoisition of the polypeptide to be expressed in the yeast strain. However, as was stated above in the rejection over Barr et al, virtually any polypeptide would contain numerous amino acids which could supplement a food source for an animal, since the provision of amino acids would supplement any food source

Therefore, the rejection is maintained.

Claims 29-37, 39 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Lei et al. (US Patent 6,451,572) (previous cited) and Dassa et al. (J. Bacteriol., 172, 9, 5497-5500, 1990, cited for evidence only).

This rejection is maintained essentially for the reasons made of record, with slight modification.

Lei teaches a transformed yeast strain comprising a nucleic acid polymer for encoding a polypeptide ordinarily exogenous to yeast (see, i.e. the appA gene of E. coli at col. 5, lines 63-64) under the control of a yeast derived promoter , said nucleic acid polymer selected from the group consisting of synthetic and natural nucleic acid polymers, and said nucleic acid encoding a polypeptide which would provide amino acids to supplement an animal feed product (see entire document, exp. Col. 5, lines 45-

67, col. 6, lines 33-37, col. 8 lines 9-56). Regarding claim 30, Lei teaches such a strain wherein expression of the polypeptide strain is inducible (se col. 8 lines 11-36). Regarding claim 31, Lei teaches such a strain wherein the polymer may be inserted into the host strain's genome , (col. 7 lines 39-41). Regarding claim 32, the polypeptide produced is retained by the transformed yeast insofar as the transformed cells do not secrete the exogenous protein (see col. 7, lines 19-34). Regarding claim 33, the transformed yeast cell is auxotrophic, but was non-auxotrophic prior to transformation, as would be the case with the use of URA 3 as a selectable marker (see col. 8, lines 50-56). Regarding claim 34, the transformed yeast strain is S. cerevisiae (see col. 6 lines 3-37). Regarding claims 35 and 39, the appA gene of E. coli encodes a polypeptide that comprises (at least) least 3 methionines, 6 histidines, 2 threonine, 2 isoleucines 1 valine, and 1 tryptophan; or 6 lysines, 3 methionines or cysteines, 2 threonines, 1 valine, 2 isoleucine, 6 histidine, and 1 tryptophan (see Dassa et al., J. Bacteriol. 172, 9, 5497-5500, 1990, Fig. 2, cited for evidence only). Regarding claim 36, a promoter utilized for the production of phytase is the GAPDH promoter (see col. 8, lines 9-18). Regarding claim 37, Lei also teaches the construct for transforming a host organism (yeast) comprising a nucleic acid polymer for encoding a polypeptide ordinarily exogenous to said organism and a promoter, wherein the nucleic acid polymer is a plasmid and is used to make a protein that would be capable of complementing a deficiency in a predetermined feed source, such as a deficiency in amino acids (i.e. protein) when added to said feed source (see e.g. col. 7, lines 36-37, and col. 8 lines 1-28). Regarding claim 43, Lei also teaches a method for producing this yeast additive

comprising inserting such a construct into a yeast strain and expressing the gene (see Ex. 4, at col. 16 and Ex. 7 at col. 20).

Applicants argue that Lei does not anticipated the claims for reasons similar to those presented in the previous sections. . However, as was stated above in the rejection over Barr et al, virtually any polypeptide would contain numerous amino acids which could supplement a food source for an animal, since the provision of amino acids would supplement any food source.

Claim Rejections - 35 USC § 103

Claims 29-39, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lei et al. ('572 patent cited above) as evidenced by Dassa et al. (cited above) in view of Sikorski et al. (Genetics 122:19-27, 1989).

This rejection is maintained essentially for the reasons made of record in the previous Office action, with claims 35 and 39 added as necessitated by applicant's amendments.

Lei et al. and Dassa et al. are cited for the reasons set forth in the above rejection.

The difference between the reference and the claims is that Lei does not teach such a construct wherein said construct is a pRS316 plasmid with a GAPDH promoter.

However, Sikorski et al. teach the use of the pRS316 plasmid for expression of proteins in yeast. Sikorski et al. teach that pRS316 comprises the URA3 selectable marker and that such a vector has the advantage that "in addition to the general features afforded

the pRS vectors by the pBLUESCRIPT backbone, such as ssDNA production, high plasmid DNA yields and extensive polylinker, unidirectional deletion formation and simplified cloning (blue/white screening for recombinants), these new vectors offer unique yeast-specific features,", i.e. the pRS316 vectors "allow one to perform almost all routine yeast DNA manipulations in the same plasmid" (see page 25, 2nd column, first full paragraph). Sikorski et al also teach that the streamlined design of the pRS vectors makes them well suited to serve as the starting point for construction of other yeast vectors (see entire document, especially paragraph bridging pages 24-25 and page 25, second column, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the pRS316 vector as taught by Skorski et al with the GAPDH promoter as taught by Lei, because Lei teaches the use of any yeast vector for production of a heterologous protein in yeast and further teaches the use of a GAPDH promoter for expression of the protein and the use of a URA3 selectable marker; Sikorski et al teach that pRS316 is a useful vector for manipulation of DNA (such as cloning) and expression of proteins in yeast and that it comprises a URA3 selectable marker.

One would have been motivated to substitute the pRS316 vector as taught by Sikorski et al in the methods taught by Lei, including the use of the GAPDH promoter, because Sikorski et al teach that the streamlined design of the pRS vectors would make DNA manipulations and cloning easier and Lei teaches that the se of the GAPDH promoter for strong production of a heterologous protein in yeast and the URA3 marker

for selection. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when utilizing the pRS316 yeast vector as taught by Sikorski et al in the methods and constructs as taught by Lei.

Applicant argues that the '572 patent fails to teach or suggest the means as recited by amended claims 29 and 37. However, for reasons set forth above, this argument is not found convincing. It is maintained that the claims are not drawn to a method of determining nutritional requirements and designing polypeptides, but rather to a yeast strain comprising any polypeptide which, when added to a food source for an animal, would supplement an amino acid deficiency of an animal diet, since the provision of multiple amino acids contained in the encoded protein of the reference, would supplement any animal feed source by providing amino acids. It is maintained that any polypeptide comprising the 26 amino acids would constitute such a polypeptide, since a food source lacking in any particular amino acid would be supplemented by said polypeptide. Therefore the rejection is maintained.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chambon et al. (US Patent 5817503) in view of Meade et al. (J. Animal Sci. 1965, 24:626-632).

Chambon et al. disclose transformed yeast strain comprising nucleic acid polymers which when expressed produce a polypeptide of interest. The difference

between the reference and the instant claims is that the polypeptide of interest comprises the amino acid units lysine, and methionine/cysteine in a ratio of 100:33. However, Meade et al. . disclose the ratios of amino acids appropriate for a diet for swine, which is identical to the above stated ratios (see page 631-632, Table 6). It would have been obvious to express any protein comprising the above stated ratios in yeast, since Chambon et al. disclose that any protein of interest can be expressed in yeast recombinantly, and since Meade et al. disclose the usefulness of proteins comprising the ratios appropriate for growth of swine. One would have been motivated to do so by the desire to produce proteins comprising a ratio of amino acids which would useful for the growth of commercially valuable animals such as chicks. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 47 and 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chambon et al. (US Patent 5,817,503) in view of Katz et al. (J. Animal Sci. 41. 1355-1361, 1975).

Chambon et al. disclose transformed yeast strain comprising nucleic acid polymers which when expressed produce a polypeptide of interest. The difference between the reference and the instant claims is that the polypeptide of interest comprises the amino acid units: lysine, arginine, histidine tryptophan, isoleucine, leucine, valine phenylalanine/tyrosine, methionine/cysteine, threonine, proline, and

glycine/serine, in a ration of 100:105:37:16:67:111:77:105: 72:67:33:67 or 100:105:37:17:67:111:77:105:75:73:20:50, wherein methionine/cysteine may be either methionine or cysteine with methionine constituting at least 50% of the sulfur-containing amino acids in the polypeptide, and phenylalanine/tyrosine may be either phenylalanine or tyrosine with phenylalanine constituting at least 50% of the aromatic amino acids in the polypeptide, and glycine/serine may be either glycine or serine.

However, Katz et al. disclose the ratios of amino acids appropriate for a diet for broiler chicks in two age categories, which is identical to the above stated ratios. It would have been obvious to express any protein comprising the above stated ratios in yeast, since Chambon et al. disclose that any protein of interest can be expressed in yeast recombinantly, and since Katz et al. disclose the usefulness of proteins comprising the ratios appropriate for growth of broiler chicks. One would have been motivated to do so by the desire to produce proteins comprising a ratio of amino acids which would useful for the growth of commercially valuable animals such as chicks. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 44, 46, 48-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
8/31/08